at least one sensor capable of sensing pH located within said catheter such that said CSF is permitted to flow adjacent said sensor;

whereby said sensor is capable of permitting monitoring of at least one characteristic, including pH, of CSF over time.

39. (Amended) The apparatus of claim 36, whereby said characteristic monitored further includes a characteristic selected from the group consisting of partial oxygen pressure, temperature, carbon dioxide concentration, and combinations thereof.--

**REMARKS**

Applicants respectfully request reconsideration of the subject application in light of the above amendments and the following remarks. Claims 10-40 are pending in this application. Claims 10-40 stand rejected in this application. Claims 10, 15, 16, 18, 21, 26, 28, 31, 34, 36 and 39 have been amended. No new matter had been added to the present application.

Claims 10-40 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. In particular, the Examiner rejected the claims based upon insufficient antecedent basis in claims 10, 15, 18, 21, 28, 31, and 36. Sufficient antecedent basis has been provided, and applicants respectfully request that this rejection be removed.

Claims 10, 11, 14, 21, 24, 31, and 36 stand rejected under 35 U.S.C. 102 (b) as being anticipated by U.S. Patent No. 5,117,836 to Millar (hereinafter "Millar"). Applicants have amended claims 10, 21, 31, and 36 to overcome this rejection. Specifically, applicants have amended the limitation to include "placing at least one sensor capable of sensing pH into said flow section within said catheter to enable said CSF to flow adjacent said sensor so that said sensor may sense at least

one characteristic, including pH, of said CSF." As "Millar does not teach that a transducer is used to monitor pH, partial oxygen pressure, temperature, or carbon dioxide concentration" (Office Action of August 20, 2002, p. 5), Applicants believe that this rejection is now moot, and respectfully request that favorable action be taken.

Claims 10-12, 21-22, 25, 31-33, and 36-38 stand rejected under 35 U.S.C. 102 (b) as being anticipated by U.S. Patent No. 4,903,707 to Knute et al. (hereinafter "Knute"). Applicants have amended claims 10, 21, 31, and 36 to overcome this rejection. Specifically, applicants have amended the limitation to include "placing at least one sensor capable of sensing pH into said flow section within said catheter to enable said CSF to flow adjacent said sensor so that said sensor may sense at least one characteristic, including pH, of said CSF." As Knute does not teach monitoring pH, Applicants believe that this rejection is now moot, and respectfully request that favorable action be taken.

Claims 15-20, 25-30, 32-35, and 37-40 stand rejected under 35 U.S.C. 103(a) as being obvious over Millar as applied to claims 10, 14, 21, 24, and 31 in view of U.S. Patent No. 4,904,237 to Janese (hereinafter "Janese"). Applicants respectfully traverse this rejection and request favorable action in view of the following remarks.

As argued above, the rejection as to Millar is now moot as applied to claims 10, 14, 21, 24, and 31 in view of the amendments above. Applicants further submit that Millar is not properly combinable with Janese, and, if combined, would not disclose the present invention.

The present invention is patentably distinguishable over Janese, both alone and in combination with Millar. Janese does not disclose a sensor received in the body of the patient as is disclosed in the present invention and "Janese does not teach that the pH probe is inserted into a

patient's brain ventricle." (Office Action of February 20, 2002, p. 7, paragraph 12). Janese merely teaches a "cannula 99 which punctures the spinal canal providing a conduit for a catheter 93 which indwells in the subarachnoid compartment of the spinal canal 33." (Janese, col. 7, lines 37-40) Further, Janese does not teach or suggest the monitoring of any CSF characteristic within the body of the patient. (Janese, Col. 6, line 53 to Col. 7, line 15).

Millar discloses "reading, storing and analyzing fluid characteristics such as chemical content, pressure, hemodynamics and waveform responses. . ." (Millar, Col. 4, lines 29-32) In the Advisory action, the Examiner states that pH falls into the categories of possible measurements as disclosed by Millar. Applicants respectfully disagree. Applicants do not believe that pH falls into the categories of chemical content, pressure, hemodynamics, and waveform responses. Further, Millar does not teach sensing chemical properties or chemical characteristics, in general, of the intracranial fluid, and more specifically, Millar does not teach sensing pH.

Applicants submit that the references, either alone or in combination, do not suggest the present invention. The Patent and Trademark Office's burden of establishing a prima facie case of obviousness is not met unless "'the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.'" In re Bell, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993) (quoting In re Rinehart, 189 U.S.P.Q. 143, 147 (C.C.P.A. 1976)). There is no suggestion or motivation in either Janese or Millar to modify the references or to combine the reference teachings. Further, combination of the teachings would not disclose the present invention. Specifically, neither Millar nor Janese disclose sensing or monitoring pH. Still further, Applicants believe that the modification of Millar in view of Janese, as suggested by the Examiner, would destroy the intended function of the prior art. That is, Janese relates generally to

an apparatus and method for exchanging cerebrospinal fluid, and the monitoring of CSF characteristics inside the body would not be conducive to the treatment of CSF outside the body for returning to the body. It is respectfully submitted that for the above reasons, Millar and Janese are not properly combinable. Therefore, claims 15-20, 25-30, 32-35, and 37-40 are believed to be in condition for allowance and it is respectfully requested that the rejection of these claims be withdrawn.

Claims 13 and 23 stand rejected under 35 U.S.C. 103 (a) as being obvious over Millar as applied to claims 10 and 21 in view of U.S. Patent 5, 830,188 to Abouleish (hereinafter "Abouleish").

As argued above, the rejection as to Millar is now moot as applied to claims 10 and 21 in view of the amendments above. Because claims 13 and 23 depend from claims 10 and 21, Applicants submit that this rejection is also moot and favorable action is respectfully requested.

In view of the foregoing, Applicant respectfully submits that the application as amended is in condition for allowance and favorable action is requested. Should the Examiner believe any issues are outstanding he is encouraged to contact the undersigned at (816)474-6550 or (800)821-7962.

Attached hereto is a marked-up version illustrating the changes made to the specification and claims by virtue of the current amendment. The attached page is captioned **"Version with markings to show changes made."**

The present Response is being filed concurrently with 1) a Petition for an Extension of Time along with a check for $205.00 for a small entity; and 2) a Request for Continued Examination along with a check in the amount of $375.00 for a small entity pursuant to 37 C.F.R.

§ 1.17(e). The Commissioner is hereby authorized to charge any additional fees that are required, or credit any overpayment, to Deposit Account No. 19-2112.

Respectfully submitted,

Jessica Aga Lambert

Jessica Aga Lambert
Reg. No. P-53,180

JHA/td

SHOOK, HARDY & BACON L.L.P.
One Kansas City Place
1200 Main Street
Kansas City, Missouri 64105-2118
816/474-6550

## Version with Markings to Show Changes Made

## In the Claims

Claims 10, 15, 16, 18, 21, 26, 28, 31, 34, 36 and 39 have been amended without prejudice or disclaimer.

10. A method of monitoring the cerebral cellular environment of a patient for prognosis and for providing information for treatment, comprising:

providing and opening in the skull of said patient;

inserting a catheter through said opening into a region of cerebrospinal fluid (CSF) within said skull of said patient, said catheter having a flow section capable of permitting said CSF to flow therein;

positioning said flow section of said catheter into said region of CSF;

placing [a] at least one sensor capable of sensing pH into said flow section within said catheter to enable said CSF to flow adjacent [the tip of] said sensor so that said sensor may sense at least one characteristic, including pH, of said CSF; and

monitoring [the] changes of said characteristic of said CSF.

15. The method of claim 14, further comprising:

draining said CSF through said catheter[; and], wherein said monitored characteristic further includes intracranial pressure.

[monitoring the intracranial pressure].

16. The method of claim 10, whereby said characteristic monitored [is] further includes a characteristic selected from the group consisting of [pH,] partial oxygen pressure, temperature, carbon dioxide concentration, and combinations thereof.

18. The method of claim 10, further comprising:

monitoring said characteristic on a continuous basis;

collecting data regarding said characteristic;

storing said data; and

comparing said data.

21. A method of monitoring at least one characteristic of cerebrospinal fluid (CSF) of a patient for prognosis and for providing information for treatment, comprising:

providing an opening in said patient through which a region of CSF is accessible;

inserting a catheter through said opening into said region of CSF in said patient, said catheter having a flow section capable of permitting said CSF to flow therein;

positioning said flow section of said catheter into said region of CSF;

placing [a] at least one sensor capable of sensing pH into said flow section within said catheter to enable said CSF to flow adjacent [the tip of] said sensor so that said sensor may sense at least one characteristic, including pH, of said CSF; and

monitoring [the] changes of said characteristic of said CSF.

26. The method of claim 21, whereby said characteristic monitored [is] further includes a characteristic selected from the group consisting of [pH,] partial oxygen pressure, temperature, carbon dioxide concentration, and combinations thereof.

28. The method of claim 21, further comprising:

monitoring said characteristic on a continuous basis;

collecting data regarding said characteristic;

storing said data; and

comparing said data.

31. An apparatus for monitoring the cerebral cellular environment of a patient, comprising:

a catheter having a wall section adapted to permit cerebrospinal fluid (CSF) to flow therein, said catheter adapted for introduction through an opening in a skull of a patient; and

[a] at least one sensor capable of sensing pH located within said catheter such that said CSF is permitted to flow adjacent [the tip of] said sensor;

whereby said sensor is capable of permitting [the] monitoring of at least one characteristic, including pH, of said CSF over time.

34. The apparatus of claim 31, whereby said characteristic monitored [is] further includes a characteristic selected from the group consisting of [pH,] partial oxygen pressure, temperature, carbon dioxide concentration, and combinations thereof.

36. An apparatus for monitoring at least one characteristic of cerebrospinal fluid (CSF) of a patient, comprising:

a catheter having a wall section adapted to permit said CSF to flow therein, said catheter adapted for introduction through an opening in said patient through which a region of CSF is accessible; and

[a] at least one sensor capable of sensing pH located within said catheter such that said CSF is permitted to flow adjacent [the tip of] said sensor;

whereby said sensor is capable of permitting [the] monitoring of at least one characteristic, including pH, of CSF over time.

39. The apparatus of claim 36, whereby said characteristic monitored [is] <u>further includes a characteristic</u> selected from the group consisting of [pH,] partial oxygen pressure, temperature, carbon dioxide concentration, and combinations thereof.